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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/504,389	02/15/2000	Mark W. Perlin	PERLIN-8	7829

7590

09/09/2003

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EXAMINER

BRUSCA, JOHN S

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/504,389

Applicant(s)

PERLIN, MARK W.

Examiner

John S. Brusca

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-20 and 22-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-20 and 22-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. This Office action contains new grounds of rejection not necessitated by the applicant's amendment and is therefore a non-final rejection.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 17-20, 22-25, 29, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Perlin et al.

The claims are drawn to a method of determining the genotype of each DNA in a mixture of DNA molecules from a plurality of individuals. The method utilizes a mathematical procedure comprising a matrix operation in linear equations. In some embodiments the method is limited to DNA molecules obtained by a process of polymerase chain reaction of a short terminal repeat locus. In some embodiments the method includes an optimization step, or a determination of the proportion of each individual DNA.

Perlin et al. shows on pages 1200-1204 a mathematical method of analysis of a mixture of pooled DNA molecules from a plurality of individuals by generation through a polymerase chain reaction of a short terminal repeat loci. Perlin et al. shows that it is possible to determine the genotype of a DNA molecule in the mixture by application of the method on pages 1207-1208. The mathematical method comprises a matrix-vector analysis. Perlin et al. shows methods of determining the optimum solution to obtain the correct genotype.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 17-20, and 22-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perlin in view of Clayton et al.

The claims are drawn to a method of determining the genotype of each DNA in a mixture of DNA molecules from a plurality of individuals suspected of perpetrating a crime.

Perlin et al. shows on pages 1200-1204 a mathematical method of analysis of a mixture of pooled DNA molecules from a plurality of individuals by generation through a polymerase chain reaction of a short terminal repeat loci. Perlin et al. shows that it is possible to determine the genotype of a DNA molecule in the mixture by application of the method on pages 1207-1208. The mathematical method comprises a matrix-vector analysis. Perlin et al. shows methods of determining the optimum solution to obtain the correct genotype. Perlin et al. does not show

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analysis of DNA samples of individuals suspected of perpetrating a crime. Perlin et al. does not explicitly show results of genotyping from mixtures of DNA.

Clayton et al. shows in the introduction on pages 56 and throughout that analysis of DNA samples comprising DNA from a plurality of individuals in forensic samples for short terminal repeat loci can serve to link suspected criminals to a crime scene. Clayton et al. shows on pages 60-65 methods to analyze genotypes in forensic samples of DNA from more than one individual. Clayton et al. shows in the appendices on pages 65-69 working examples of identification of genotypes from forensic samples of DNA from more than one individual.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the method of Perlin et al. to analyze forensic samples because Clayton et al. shows that forensic samples often comprise DNA of multiple individuals and Perlin et al. shows a method of identifying individual short terminal repeat patterns in a mixture of DNA from a plurality of individuals that has improved features over prior art methods. It would have been further obvious to determine the genotype of individuals from whom the samples were derived because Perlin et al. shows that their method has advantages of analyzing stutter results of amplifications, Perlin et al. shows that their method can be used to determine genotypes of individuals from whom mixed DNA samples were derived, and because Clayton shows general methods and working examples of determining genotypes of individuals from mixed DNA samples for the purpose of forensic identification.

Response to Arguments

6. Applicant's arguments filed 01 August 2003 have been fully considered but they are not persuasive. The applicant states that Perlin et al. does not show determination of genotypes of a

plurality of individuals, however Perlin et al. shows deconvolution of pooled marker DNA on page 1203, and shows a working example of deconvolution of genotypes on pages 1207-1208. In the discussion on pages 1208-1209, Perlin et al. states that the method can be used for deconvolution for both single genotype applications and pooled genotyping. Clayton et al. further show determination of genotypes of individuals from mixed DNA samples.

Double Patenting

7. It is noted that the Office action mailed 31 August 2003 contains an error in citation of a copending application. The copending application number was incorrectly indicated as 09/779096, and should have been indicated as 09/776096. The rejection detailed below is revised to cite the correct copending application.

8. The warning concerning duplicate claim 21 in the Office action mailed 31 January 2003 is withdrawn in view of the cancellation of claim 21 in the amendment filed 01 August 2003.

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 17-20 and 22-30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5-8, and 21 of copending Application No. 09/776096 in view of Perlin et al.

This is a provisional obviousness-type double patenting rejection.

The claims are drawn to a method of determining the genotype of each DNA in a mixture of DNA molecules from a plurality of individuals. The method utilizes a mathematical procedure comprising a matrix operation in linear equations. In some embodiments the method is limited to DNA molecules obtained by a process of polymerase chain reaction of a short terminal repeat locus. In some embodiments the method includes an optimization step, or a determination of the proportion of each individual DNA, the DNA samples are from a forensic sample, the relative weight of the different DNA in the mixture is determined, the genotype of the DNA is determined, and a statistical confidence of the genotype is determined.

Claims 1, 5-8, and 21 of copending Application No. 09/776096 are drawn to a method of determining the genotype of each DNA in a mixture of DNA molecules from a plurality of individuals. The method utilizes a mathematical procedure comprising a matrix operation in linear equations. In some embodiments the method determines the confidence of the determination, the genotype of the DNA, the weight of an individual DNA in a mixture, and use

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of the method to identify suspected criminals. The claims are not drawn to method utilizing short terminal repeat analysis of a PCR sample, or optimization of the result.

Perlin et al. shows on pages 1200-1204 a mathematical method of analysis of a mixture of stutter DNA molecules generated by polymerase chain reaction of a short terminal repeat locus. Perlin et al. shows methods of determining the optimum solution to obtain the correct genotype on pages 1204-1205.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of claims 1, 5-8, and 21 of copending Application No. 09/776096 by use of PCR analysis of short terminal repeats and optimization because Perlin et al. shows that such methods are useful to analyze DNA samples to determine genotypes present in the sample.

Terminal Disclaimer

11. The application/patent being disclaimed has been improperly identified since the number used to identify the application being disclaimed is incorrect. The correct number is 09/776096 as detailed above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 703 308-4231. The examiner can normally be reached on M-F 8:30-5:00.

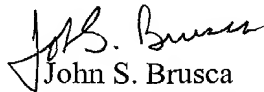
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703 308-4025. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.


John S. Brusca
Primary Examiner
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jsb